

# **Exhibit 5**

*Can you send me your certification / FDA approval?*

The FDA does not regulate, nor certify, repairs. The FDA regulates 3<sup>rd</sup> party reprocessing companies and single-use devices. The FDA definition of a single-use device is as follows: "A single-use device, also referred to as a disposable device, intended for use on one patient during a single procedure. It is not intended to be reprocessed (cleaned, disinfected/sterilized) and used on another patient. The labeling may or may not identify the device as single use or disposable and does not include instructions for reprocessing." The FDA only classifies devices as single-use or reusable (multiple-use). By these definitions, the EndoWrist® instruments are classified as multiple-use instruments, servicing these instruments does not meet the definition of a reprocess. All of the "reprocessing" of these instruments is, and will always remain, the responsibility of the end users. They are intended to be cleaned and sterilized at the hospital facility. The intended use and cleaning/sterilization procedure remains the same for these instruments. We do not sell any product. We only repair instruments for the hospital, with no change of ownership. In the USA this is controlled via the hospital quality system and the Joint Commission. EU and most countries are similar to USA in this regard. Hospitals typically request our ISO certification (this is the norm for service providers), and we can provide current certificates upon request.

*What does your service provide?*

The Rebotix™ service is a complete repair of the da Vinci® EndoWrist® instruments. The instruments are sold with a use counter which limits the life of the instrument. Upon reaching a zero count the instruments are "expired" and rendered useless and must be discarded.

This service provides the resetting of the use counter via a replacement chip (Interceptor), provided by Rebotix™, extending the life of the instrument. Additionally, it also offers a complete evaluation and repair of the distal/tool end of the instrument. The replacement chips, as well as the service process, were designed and developed under a formal quality system ensuring the serviced instruments meet the quality and functional requirements of a new device. Formal, independent testing and validation on the replacement chips were conducted to ensure the intended use and performance are equivalent to that of the OEM device.

*What do we need to know to collect instruments for service?*

Upon receiving an instrument for the initial repair, the instrument must arrive with one use left. If the instrument reaches zero (0) it "expires". The OEM instructs the machine to erase the data on the instrument to prevent it from being used further. In order for the reset to be performed the data must be retained on the initial repair, however once the reset has been performed once, the instrument can be used up to expiration (and retain its original data) and maintain the ability to be reset.

*What instrument models are supported?*

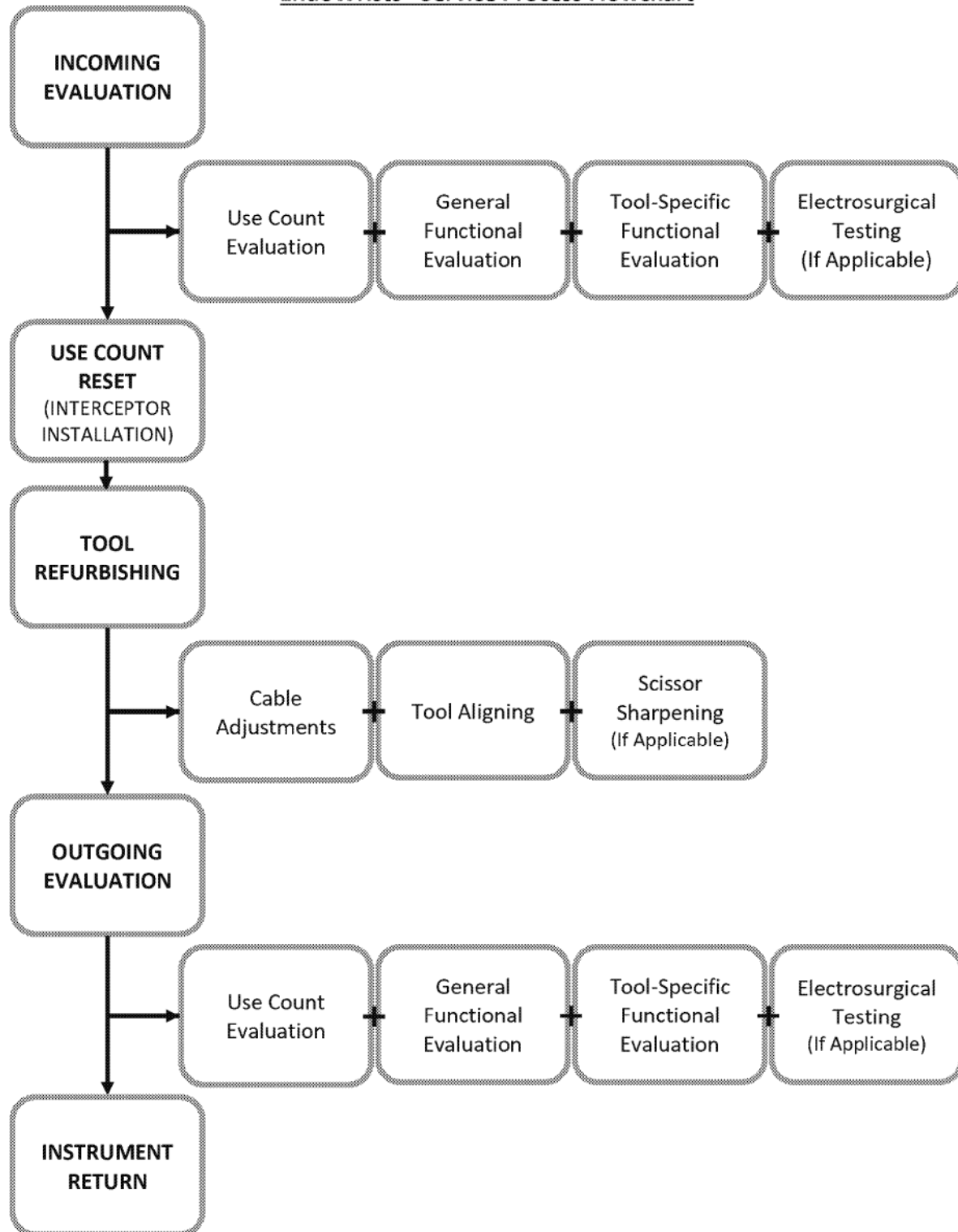
This list is continually maintained, so check back if you have questions about an instrument not on this list:

**Compatible EndoWrist® Instruments**

420001 Potts Scissors  
420003 Small Clip Applier  
420006 Large Needle Driver  
420007 Round Tip Scissors  
420033 Black Diamond Micro Forceps  
420036 DeBakey Forceps  
420048 Tip Forceps  
420049 Cadiere Forceps  
420093 ProGrasp Forceps  
420110 PreCise Bipolar Forceps  
420121 Fine Tissue Forceps  
420157 Snap-fit™ Scalpel Instrument  
420171 Micro Bipolar Forceps  
420172 Maryland Bipolar Forceps  
420178 Curved Scissors  
420179 Hot Shears (Monopolar Curved Scissors)  
420181 Resano Forceps  
420183 Permanent Cautery Hook  
420184 Permanent Cautery Spatula  
420189 Double Fenestrated Grasper  
420190 Cobra Grasper  
420192 Valve Hook  
420194 Mega Needle Driver (Tapered)  
420203 Pericardial Dissector  
420204 Atrial Retractor  
420205 Fenestrated Bipolar Forceps  
420207 Tenaculum Forceps  
420215 Cardiac Probe Grasper  
420227 PK® Dissecting Forceps  
420230 Large Clip Applier  
420246 Atrial Retractor Short Right  
420249 Dual Blade Retractor  
420278 Graptor (Grasping Retractor)  
420296 Large SutureCut™ Needle Driver  
420309 Mega™ SutureCut™ Needle Driver  
420318 Small Graptor (Grasping Retractor)  
420327 Medium-Large Clip Applier  
420344 Curved Bipolar Dissector

*Can you describe your service process?*

**EndoWrists® Service Process Flowchart**



Additional information:

- EndoWrist® functionality and safety are not affected by the repair
  - Extensive analysis and formal testing were performed to assure that there were no unintentional side effects
  - Repaired instruments have been subjected to all appropriate ISO 10993 biocompatibility tests (by a certified independent test laboratory) and passed
  - Electrical and electro-surgical safety have been carefully considered per the expectations in the safety standards, and special fixtures are used during service to retest the instrument to a production equivalent qualification
- Service components are built with quality standards meeting medical device expectations, including
  - ISO 9001:Quality Systems Model for QA in Design/Development, Production, Installation, and Servicing
  - ISO 9002:Quality Systems Model for QA in Production and Installation
  - ISO 9003:Quality Systems Model for QA in Final Inspection and test
  - ISO 9001:Quality Management Systems
- The service process is performed under a formal quality control system certified per ISO 9001, with all assembly operations and testing done per formal procedures
- Rebotix provides continuing technical support to assure the final quality of the serviced instruments, and will monitor and respond to any reported field issues using a formal surveillance system
- Validated fixtures and tools can be provided to repeat safety testing in the hospital, if desired